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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/047,817 | 01/15/2002 | Richard Allen Brown | 214967 | 4741 |

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER

CAPPS, KEVIN J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/047,817 | Applicant(s) BROWN, RICHARD ALLEN | |
| | Examiner Kevin Capps | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-9, 11-32 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-9, 11-32 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. This Office Action is in response to the Remarks and Fourth Declaration Under 37 C.F.R. § 1.132 filed on August 9, 2006. Claims 1, 7-9, 11-32, and 53-58 are pending and examined on the merits herein.
2. Claims 1, 7-9, 11-32, and 53-58 stand rejected under 35 USC § 103 over Stepniewski et al. (US 5,599,533) in view of Rappoport (US 5,730,991), and further in view of Dorogi et al. (US 5,882,661). The rejection is maintained. Applicant's arguments and the declaration are addressed below.
3. Claims 1, 7-9, 11-32, and 53-58 stand rejected under 35 USC § 103 over Stepniewski et al., Rappoport, and Dorogi et al. as applied to claims 1, 7-9, 11-32 and 53-58, and further in view of Collin et al. (US 5,656,672). The rejection is maintained. Applicant's arguments and the declaration are addressed below.

Response to Arguments

4. Applicant's arguments filed August 9, 2006, have been fully considered but they are not persuasive.
5. Regarding the rejection of claims 1, 7-9, 11-32, and 53-58 under 35 USC § 103 over Stepniewski et al. (US 5,599,533) in view of Rappoport (US 5,730,991), and further in view of Dorogi et al. (US 5,882,661), Applicant asserts that the instantly claimed compositions are not obvious in view of the combined reference because Applicant has

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discovered that incorporation of the emulsifier cetyl dimethicone copolyol in the range of 3-6% by weight has improved stability relative to other concentrations of the emulsifier that are within the range disclosed by Stepniewski et al.. Applicant points to the Declaration filed under CFR 37 § 1.132 on August 9, 2006, as evidence of an enhanced stability of compositions comprising the herein-claimed concentrations of cetyl dimethicone copolyol relative to compositions comprising concentrations of the emulsifier that are within the range disclosed by Stepniewski et al. The Examiner acknowledges that the Declaration indicates an enhanced stability of the instantly claimed composition comprising cetyl dimethicone copolyol at 3-6% by weight relative to similar compositions that comprise concentrations of cetyl dimethicone copolyol outside of the herein-claimed range, but within the range disclosed by Stepniewski et al.

However, as discussed in the previous Office Action, it is a matter of routine experimentation to test various concentrations of the emulsifier from within the range taught by Stepniewski et al. to arrive at the optimal range from within the broad disclosure. Applicant's attention is directed to *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) which states, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05, "II. Optimization of Ranges".

6. The Examiner provided a new ground of rejection in the previous Office Action using Stepniewski et al., Rappoport, and Dorogi et al. in view of Collin et al. to illustrate that emulsions comprising the herein-claimed concentration of cetyl dimethicone copolyol were recognized in the art. Collin et al. exemplify the use of cetyl dimethicone

copolyol as an emulsifier in a dermatological formulation at a concentration within the herein-claimed preferred range. In traversing the rejection, Applicant argues that, "Collin et al. relates to maintaining stability and activity of retinol acne formulations with an organic solvent. Cetyl dimethicone copolyol is added as an emulsifier to the water-in-oil emulsion. Collin et al. reports that it is the organic solvent—and not the cetyl dimethicone copolyol—that stabilizes the retinol. Collin et al. does not teach or suggest that cetyl dimethicone copolyol provides any stability to the water-in-oil emulsion itself, as in the present invention." (p. 5 of Remarks). Applicant concludes that, "As a result, the ordinarily skilled artisan would not be pointed to the disclosure of Collin et al. since it pertains to maintaining retinol activity and not emulsion stability." (p. 5 of Remarks). As Applicant notes, Collin et al. discloses preferred organic solvents for stabilizing the notoriously unstable retinol. However, the organic solvent stabilizes the retinol, not the emulsion itself. The emulsion is stabilized by the inclusion of the emulsifier cetyl dimethicone copolyol. Applicant acknowledges that the cetyl dimethicone copolyol is added as an emulsifier. The person of ordinary skill recognizes that the function of an emulsifier is to stabilize an emulsion. For instance, see www.ucalgary.ca/~schramm/emulsion.htm, which defines an emulsifier as, "An agent that acts to stabilize an emulsion. The emulsifier may make it easier to form an emulsion and to provide stability against aggregation and possibly against coalescence." Thus, by Applicant's own admission, in view of the art-recognized definition of emulsifier, the cetyl dimethicone copolyol was added to the compositions of Collin et al. to stabilize the emulsion. Further, Collin et al. exemplify a concentration of

the emulsifier cetyl dimethicone copolyol that is within the herein-claimed range. Thus, the person of ordinary skill in the art would understand upon viewing Collin et al. that cetyl dimethicone copolyol could be incorporated into water-in-oil emulsions at the herein-claimed range in order to achieve enhanced stability of the emulsion.

Conclusion

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7:30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KC

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath the name.

**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**